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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1773

NOTIFICATION DATE

DELIVERY MODE

10/07/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/581,409

Applicant(s)

PACHL ET AL.

Examiner

LYLE ALEXANDER

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 22-36 and 40-42 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 22-36 and 40-42 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 22-25, 29-36 and 40-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Markart

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 22 requires the elevation/depression range from "about 50nm to 100nm". Dependent claim 26 does not further limit claim 22 with the claimed ranged from "about 50nm to 200nm". For the purposes of examination, the claimed range will be interpreted as "about 50nm to 100nm".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 22-36 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markart et al. (USP 6,441,898).

Markart teaches an analytical test element(18) for the measurement of blood glucose. Column 5 lines 3+ describe the construction of the test strip in figures 2-4. The strip(18) comprises carrier web(26) that is covered with reagent/paint layer(34) and diaphragm strips(30) on both ends. The left end of the strip is a surface(32) that is used for standardization. The area between the two diaphragm strips are the reaction field. There is an aperture (40) in the hydrophobic outer surface (38) where the blood sample is applied. Over the reaction field and below the aperture is the hydrophilic inner layer(36) that spreads the sample over layer(36). Figure 4 shows there is a gap between the inner layer(36) and the reaction field(34).

The Office has read the claimed "*inert carrier*" on the taught **web (26)**, the claimed "*application zone*" on the taught **opening (40)**, the claimed "*channel gap*" on the taught **gap between layer (36) and the reaction field** and the "*hydrophobic structure*" on the taught **outer surface (38)**.

Markart et al. are silent to the claimed "distance between elevation ... 50nm-200 microns ... average height ... 50nm-100 microns ...", the hydrophobic surface energy less than or equal to 10nM/m and the hydrophobic contact angle greater than 120'.

MPEP 2144.05(II)(B) states that optimization of a result effective variable is ordinarily within the skill of the art. A result-effective variable is a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine

experimentation. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) and also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The selection of the surface roughness, is a result effective variable with the well known and expected results relating to the speed and turbulence of a fluid flow. The more rough the surface, the slower and more turbulent will be the fluid flow. It would have been within the skill of the art to modify Markart and make the surface have a roughness with a "distance between elevation ... 50nm-200 microns ... average height ... 50nm-100 microns ..." as optimization of a result effective variable to achieve the desired fluid flow speed and turbulence.

The selection of the surface energy and contact angle relate to the extent of hydrophobicity. Depending on the characteristics of the test fluid, such as viscosity, the hydrophobic characteristics of the surface will need to be optimized. It would have been within the skill of the art to further modify Markart to have a surface energy less than or equal to 10nM/m and the hydrophobic contact angle greater than 120° as optimization of a result effective variable to achieve the well known and expected results of the desired hydrophobicity for the specific type of sample.

Response to 1.132 Declaration

4. Applicant's 1.132 Declaration filed 8/24/11 have been fully considered but is not persuasive.

5. Applicant's Declaration is deficient because "Exhibit A" that is referenced to show the unexpected results is not present in the file. Applicant should resubmit the Declaration with the attached "Exhibit A".
6. The Office agrees the 8/24/11 1.132 Declaration appears to be commensurate in scope with the pending claims, but is incomplete as described above. However, for the sake of argument the Office will assume the above referenced "Exhibit A" is similar to the "Exhibit A" submitted with the 8/11/11 1.132 Declaration. The Office tentatively agrees the figure 3a exhibits unexpected results in comparison to figure 3b. Upon viewing figure 3c, the results appear to be very similar to the instant invention, as depicted by figure 3a. Applicant states in the 8/24/11 Declaration on page 4 in paragraphs "e" through "g", the resolution of "Exhibit A" is not high enough to see the differences between figures 3a and 3c, but the differences are clearly apparent upon examination of the actual test elements. The Office is requesting new photographs that are of high enough resolution to show the unexpected results of the instant invention.
7. If the 8/24/11 1.132 Declaration is re-submitted with an exhibit/photographs that show the difference between examples 3a and 3c, the art of record may be overcome.
8. Applicant did not make any further remarks that require consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1269. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797